

Remarks

Claims 62, 69, 76, and 116-139 are presented for the Examiner's review and consideration.

Claims 62, 116, 125, 126, and 134 have been amended, and claims 135-139 have been added.

35 U.S.C. §112 Rejections

Claims 118, 122, 128, and 132 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner stated that it is not clear what is meant by the language "expanding the implant into the tissue" or "expanding the implant into the bone" as now claimed. In response, Applicant respectfully submits that this rejection should be withdrawn.

Applicant discloses that the implant expands radially outwardly into the tissue or bone space and creates a mechanical interlock. (p. 32, lines 8-9). This feature of the invention is illustrated in Figures 10A and 10B. As provided in Merriam-Webster Online Dictionary, the word "into" (as used above) means "in the direction of" and "to a position of contact with." Therefore, the implant expands "in the direction of" the tissue and ultimately expands "to a position of contact with" the tissue to create a mechanical interlock.

Applicant respectfully contends that the specification fully supports and explains the rejected claim language. Also, the dictionary meaning of the word "into" provides further clarification as to the meaning of the claim language.

35 U.S.C. §102 Rejection based on Kensey

Claims 62, 69, 76, 116-119, 124-129, and 134 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,890,612 to Kensey (hereinafter "Kensey"). Specifically, the Examiner stated that "Kensey anticipates the claim language where the puncture and surrounding area is the implantation site as claimed, and the expansion occurs by absorbing the liquid of blood at the implantation site." In response, Applicant respectfully submits that this rejection should be withdrawn.

Kensey discloses a device and method for sealing a puncture or incision formed

percutaneously in tissue separating two internal portions of the body of a living being, such as punctures or incisions in blood vessels, ducts or lumens, gall bladders, livers, hearts, etc. (col. 2, lines 38-42). The device includes a closure member and a retraction filament connected thereto. (col. 4, lines 16-19). In use, the device is inserted within an artery by way of a tubular body. A pusher pushes the device through the tube forcing it out the end of the tube and into the artery. Once the device is outside the confines of the tubular body, it expands or enlarges to its disk-shaped configuration. After the tubular body is withdrawn from the patient's body, a substantial portion of the filament is outside the patient's body. The filament is pulled to cause the device to move toward the puncture, until it is in intimate engagement with the tissue contiguous with the puncture. This action hemostatically seals the puncture. (col. 5, lines 37-58).

In another embodiment, the closure includes a holding member, a filament, and a sealing member. (col. 6, lines 29-31). As described above, a plunger is operated to expel the closure. Once the closure is expelled, it is held in this position for a short period of time, e.g., 15 to 60 seconds, to allow the foam at the tip of the closure to swell. The insertion device is then removed and the filament is then retracted. This action pulls the closure back through the puncture or incision in the artery wall. (col. 7, lines 1-25).

In contrast, Applicant discloses devices for stabilization surgery and their methods of use. These prosthetic devices may be made of an expandable material. (p. 31, lines 17-25). Expansion can take place in one of two ways. The device itself can be compressed and then expand when placed in the body. Alternatively, the device may be made of a material which expands when it comes in contact with water or other bodily fluid. (p. 30, line 23 to p. 31, line 3). The implant is placed into a tissue space defined by an edge in host tissue. The implant expands into the host site, without the necessity of damaging the tissue further through some other kind of attachment means. (p. 32, lines 8-14). As seen in Figures 10A, 10B, 11A, and 11B, the expandable material expands while the implant is at the host site.

Applicant respectfully contends that Kensey fails to teach or suggest all the claim elements of amended independent claims 62 and 125. As described above, Kensey discloses an implant which is inserted into the body by way of a tubular body. The implant is first permitted to expand by absorbing body fluid. Then, the implant is positioned within the puncture site.

Applicant, on the other hand, positions the implant at an implantation site, then allows the implant to expand. In the Office Action, the Examiner described Kensey's "puncture and surrounding area" as the implantation site. The Examiner has broadly defined the term "implantation site" to include the site where Kensey's device expands and the site where Kensey's device is ultimately positioned. Conversely, Applicant defines "implantation site" as, only, the site where Applicant's implant ultimately resides after implantation. To avoid any confusion about the term "implantation site" and to further clarify the present invention, Applicant has amended independent claims 62 and 125 to include, *inter alia*, positioning an implant at a host site and expanding the implant at the host site.

In addition, as mentioned above, Kensey's implant includes a retraction filament for pulling the closure member or sealing member into the puncture site. A portion of the filament extends outside the patient's body. Figures 4, 9, and 12 of Kensey further show the filament extending from the patient's body. Applicant, on the other hand, positions an implant into a tissue or bone space. As seen in Figures 10A and 10B, the implant is completely placed within the host site, *i.e.* no part of the implant extends outside the patient's body. To highlight this distinction, Applicant has amended claims 62 and 125 to include, *inter alia*, positioning an implant entirely within a patient's body.

Based on the above remarks, Applicant respectfully submits that amended claims 62 and 125 are patentably distinct over Kensey. Based on at least their dependency, Applicant also submits that claims 69, 76, 116-124, and 126-134 are allowable as well.

35 U.S.C. §102 Rejection based on Draenert

Claims 62, 69, 76, and 116-134 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,084,050 to Draenert (hereinafter "Draenert"). Specifically, the Examiner stated that Draenert meets the claim language where the implantation site is in bone and the sheath swells or expands when contacted with body fluids. In response, Applicant respectfully submits that this rejection should be withdrawn.

Draenert discloses an implant for treating bone fractures where the implant preferably takes the shape of a hollow body. The hollow body can be securely anchored in the bone by screwing in

a bone screw or locking a wedge, peg or bone cylinder such as a cartilage bone cylinder or a ligament bone cylinder, or by inserting, screwing in or injecting an interchangeable medication and/or radiation therapy vehicle. The hollow body's lumen is provided with the appropriate internal structure for this purpose. (col. 3, lines 4-11). The lumen may have an internal diameter of 2.5-3.5 mm. (col. 7, line 57).

In contrast, Applicant discloses devices for stabilization surgery and their methods of use. These prosthetic devices may be made of an expandable material. (p. 31, lines 17-25). As seen in Figures 10A and 10B, the implant is a non-hollow or solid implant. It should be understood that in this context the term "solid" means "being without an internal cavity" as defined in Merriam-Webster Online Dictionary and as seen in Figures 10A and 10B.

To highlight this distinction, Applicant has amended independent claims 62 and 125 to include, *inter alia*, positioning a solid implant in a patient's body. In light of the foregoing, Applicant respectfully submits that amended claims 62 and 125 are patentably distinct over Draenert. Based on at least their dependency, Applicant submits that claims 69, 76, 116-124, and 126-134 are allowable as well.

New Claims

Applicant has added claims 135-139 to the application. New independent claim 135 is directed to, *inter alia*, expanding the implant to create a mechanical interlock between the implant and tissue independent of additional attachment means. Support for this claim and dependent claims 136-139 may be found throughout the specification with emphasis on p. 32, lines 11-14.

Conclusion

The Examiner requested a list of related co-pending applications and a copy of such co-pending claims. The following table lists the co-pending applications. Copies of the claims for these applications are attached.

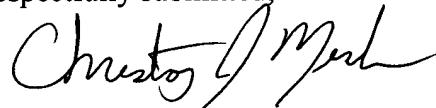
Application No.	Date Filed	Attorney Docket
10/279,402	Oct 24, 2002	780-A02-006-13
10/279,451	Oct 24, 2002	780-A02-006-14

10/371,265	Feb 21, 2003	780-A02-006-16
10/793,266	Mar 4, 2004	780-A04-006-17
10/793,265	Mar 4, 2004	780-A04-006-18
10/793,287	Mar 4, 2004	780-A04-006-19
09/872,526	Jun 1, 2001	780-A02-014-7
10/003,996	Nov 15, 2001	780-A02-014-8
10/004,905	Dec 5, 2001	780-A02-014-10
10/104,250	Mar 22, 2002	780-A02-014-12
10/233,866	Sep 3, 2002	780-A02-014-13

In light of the foregoing, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$180.00 is believed to be due for an Information Disclosure Statement that was electronically filed on even date herewith. The required fee was paid electronically via Credit Card. Please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-006-11).

Respectfully submitted,



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Enclosures



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

Confirmation No.: 9219

Application No.: 09/988,954

Attorney Docket No: 780-A02-006-11

Filed: November 21, 2001

Group Art Unit: 3738

For: TISSUE STABILIZATION METHOD

Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/279,402 (780-A02-006-13)**

2. The method of claim 13 wherein the tissue elements include bone tissue.
3. The method of claim 13 wherein the tissue elements include tendon tissue.
4. The method of claim 13 wherein the retaining structure is a mesh.
5. The method of claim 13 wherein the retaining structure includes a plurality of crossed filaments.
6. The method of claim 13 wherein the retaining structure includes a plurality of longitudinally extending filaments.
7. The method of claim 13 wherein the retaining structure includes a plurality of openings for tissue ingrowth.
9. The method of claim 13 wherein the retaining structure is made from a biodegradable material.
10. The method of claim 13 wherein the retaining structure is made of a material that expands after being compressed.

11. A method for tissue grafting comprising the steps of:
 - obtaining tissue elements from at least one human body;
 - enclosing the tissue elements with a retaining structure to form a tissue graft with a first configuration;
 - shaping the tissue graft to a second configuration; and
 - implanting the tissue graft in the second configuration in a patient,
wherein the retaining structure is made from material selected from a group consisting of ceramic, polymeric material, metal, and composite material,
wherein the retaining structure is made of a material that expands upon contact with a liquid.
12. A method for tissue grafting comprising the steps of:
 - obtaining tissue elements from at least one human body;
 - enclosing the tissue elements with a retaining structure to form a tissue graft with a first configuration;
 - shaping the tissue graft to a second configuration; and
 - implanting the tissue graft in the second configuration in a patient,
wherein the retaining structure is made from PEEK.
13. A method for tissue grafting comprising the steps of:
 - obtaining tissue elements from at least one human body;
 - enclosing the tissue elements with a retaining structure;
 - shaping the tissue elements with the retaining structure to form a grafting material having a predetermined configuration; and
 - implanting the grafting material in a patient,
wherein the retaining structure includes a bone-growth enhancer and is made from material selected from a group consisting of ceramic, polymeric material, metal, and composite material.
14. The method of claim 13 wherein the retaining structure includes hydroxyapatite.
15. The method of claim 13 wherein the shaping step includes compressing the tissue

elements with the retaining structure to form the grafting material.

16. The method of claim 15 wherein the compression of the tissue elements with the retaining structure increases the density of the tissue elements.
17. The method of claim 15 wherein compression of the tissue elements with the retaining structure forces fluid out of the tissue elements.
18. The method of claim 15 further comprising the step of cooling the tissue elements during compression.
19. The method of claim 15 further comprising the step of heating the tissue elements during compression.
21. The method of claim 23 wherein the shaping step includes compressing the first and second tissue elements to form a composite graft.
22. The method of claim 21 wherein the compression increases the density of the composite graft.
23. A method for tissue grafting comprising the steps of:
 - obtaining a first tissue element from at least one human body;
 - obtaining a second tissue element of a different tissue type than the first tissue element;
 - placing the first and second tissue elements in a forming chamber having a predetermined shape, wherein the forming chamber is a press having first and second forming elements and the first and second tissue elements are compressed between the first and second forming elements;
 - shaping the first and second tissue elements together in the forming chamber to form a composite graft having the predetermined shape, wherein the shaping step includes compressing the first and second tissue elements to form a composite graft and wherein the compression increases the density of the composite graft;

removing the composite graft from the forming chamber; and
implanting the composite graft in a patient.

24. The method of claim 21 further comprising the step of cooling the first and second tissue elements during compression.

25. The method of claim 21 further comprising the step of heating the first and second tissue elements during compression.

26. The method of claim 21 wherein the composite graft is larger than each of the first and second tissue elements.

27. The method of claim 23 wherein one of the tissue elements comprises cortical bone and the other tissue element comprises cancellous bone.

29. The method of claim 23 wherein the first and second tissue elements have a combined volume prior to shaping and the composite graft has a volume substantially equal to the combined volume.

30. A method for tissue grafting comprising the steps of:
obtaining a first tissue element from at least one human body;
obtaining a second tissue element of a different tissue type than the first tissue element;
placing the first and second tissue elements in a forming chamber having a predetermined shape;
shaping the first and second tissue elements together in the forming chamber to form a composite graft having the predetermined shape;
removing the composite graft from the forming chamber;
implanting the composite graft in a patient; and
at least partially enclosing the composite graft with a retainer prior to implantation.

31. The method of claim 30 wherein the retainer has openings to enable tissue to grow

through the openings after the composite graft is implanted in a patient.

32. A method for tissue grafting comprising the steps of:
 - obtaining a first tissue element from at least one human body;
 - obtaining a second tissue element of a different tissue type than the first tissue element;
 - placing the first and second tissue elements in a forming chamber having a predetermined shape;
 - shaping the first and second tissue elements together in the forming chamber to form a composite graft having the predetermined shape;
 - removing the composite graft from the forming chamber;
 - implanting the composite graft in a patient; and
 - at least partially enclosing the first and second tissue elements with a retainer prior to shaping.
33. The method of claim 32 further comprising the step of expanding the retainer and at least one of the first and second tissue elements in the retainer after the composite graft is implanted in a patient.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

Confirmation No.: 9219

Application No.: 09/988,954

Attorney Docket No: 780-A02-006-11

Filed: November 21, 2001

Group Art Unit: 3738

For: TISSUE STABILIZATION METHOD

Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/279,451 (780-A02-006-14)**

1. An implantable device comprising:
a first tissue element harvested from an individual;
a carrier; and
a therapeutic substance,
wherein the first tissue element, carrier and therapeutic substance are combined in a closed forming chamber having a configuration and wherein the first tissue element, carrier, and therapeutic substance form a unitary implant having a configuration which corresponds to the configuration of the forming chamber.
2. The implantable device of claim 1 wherein the therapeutic substance is selected from a group which consists of antibiotics, bone growth enhancers, tricalcium phosphate, fibrin, allograft material and autograft material.
3. The implantable device of claim 2 wherein the therapeutic substance is a bone growth enhancer.
4. The implantable device of claim 3 wherein the first tissue element is bone tissue.
5. The implantable device of claim 4 wherein the implant has a predetermined shape prior to

implantation in a patient.

7. The implantable device of claim 5 wherein the first tissue element, carrier, and therapeutic substance are compressed together.
8. The implantable device of claim 5 wherein the carrier is a gelatin or a polysaccharide.
9. The implantable device of claim 5 wherein the bone tissue is viable.
10. The implantable device of claim 5 further including a retainer at least partially enclosing the first tissue element, carrier and therapeutic substance.
11. The implantable device of claim 10 wherein the retainer has openings to enable tissue to grow through the openings after the device is implanted in a patient.
12. The implantable device of claim 10 wherein the retainer is made of an expandable material.
13. The implantable device of claim 12 wherein the retainer is made of a material that expands upon contact with body fluids.
14. The implantable device of claim 10 wherein the retainer is made of PEEK.
15. The implantable device of claim 10 wherein the retainer is made of a biodegradable material.
16. The implantable device of claim 10 wherein the retainer is made of an allograft.
17. The implantable device of claim 10 wherein the retainer is a cage.
18. An implantable device comprising:

a plurality of bone tissue pieces;
a carrier; and
a therapeutic substance,
wherein the plurality of bone tissue pieces, carrier and therapeutic substance are combined in a closed forming chamber having a configuration and wherein the plurality of bone tissue pieces, carrier and therapeutic substance form a unitary implant having a configuration which corresponds to the configuration of the forming chamber.

19. The implantable device of claim 18 wherein the therapeutic substance is selected from a group which consists of antibiotics, bone growth enhancers, tricalcium phosphate, fibrin, allograft material and autograft material.

21. The implantable device of claim 18 wherein the plurality of bone tissue pieces, carrier, and therapeutic substance are compressed together.

22. The implantable device of claim 21 wherein the carrier is a gelatin or a polysaccharide.

23. The implantable device of claim 21 wherein the bone tissue is viable.

24. The implantable device of claim 21 further including a retainer at least partially enclosing the bone tissue pieces, carrier and therapeutic substance.

25. The implantable device of claim 24 wherein the retainer has openings to enable tissue to grow through the openings after the device is implanted in a patient.

26. The implantable device of claim 24 wherein the retainer is made of an expandable material.

27. The implantable device of claim 24 wherein the retainer is made of a material that expands upon contact with body fluids.

28. The implantable device of claim 27 wherein the retainer is made of PEEK.
29. The implantable device of claim 24 wherein the retainer is made of a biodegradable material.
30. The implantable device of claim 24 wherein the retainer is made of an allograft.
31. An implantable device comprising:
 - at least one tissue element harvested from an individual;
 - a carrier for holding the tissue element;
 - a therapeutic substance incorporated into the tissue element,
 - wherein the implantable device swells at an implantation site.
32. The implantable device of claim 31 wherein the device swells after being compressed.
33. The implantable device of claim 31 wherein the device swells by imbibing liquid.



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For: TISSUE STABILIZATION METHOD

Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/371,265 (780-A02-006-16)**

11. An implantable cage for holding an implantable material, the cage comprising:
a chamber configured and dimensioned to receive the implantable material; and
at least one side wall defining the chamber,
wherein an implantable material is disposed in the chamber and the implantable material
expands when contacted with liquid.
12. The cage of claim 11 wherein the cage is made of allograft.
13. The cage of claim 12 wherein the at least one side wall has a generally cylindrical shape.
14. The cage of claim 11 wherein the at least one side wall includes a series of openings for
tissue ingrowth.
15. The cage of claim 14 wherein the at least one side wall is a mesh.
19. The cage of claim 12 wherein the at least one side wall includes a series of openings.
20. The cage of claim 19 wherein the at least one side wall is a mesh.

21. An implantable cage for holding an implantable material, the cage comprising:
a chamber configured and dimensioned to receive the implantable material; and
at least one side wall defining the chamber and including a plurality of first filaments
generally parallel to each other and a plurality of second filaments generally parallel to each other
and intersecting the plurality of first filaments to form a plurality openings in the at least one side
wall,
wherein an implantable material is disposed in the chamber and the implantable material
expands when contacted with liquid.

22. The cage of claim 21 wherein the cage is compressible.

23. The cage of claim 22 wherein the at least one side wall is a mesh.

24. The cage of claim 22 wherein the cage is made of a polymeric material.

25. The cage of claim 24 wherein the polymeric material is a synthetic polyester textile fiber.

28. An implantable cage for holding an implantable material, the cage comprising:
a chamber configured and dimensioned to receive the implantable material; and
at least one side wall defining the chamber and including a plurality of first filaments
generally parallel to each other and a plurality of second filaments generally parallel to each other
and intersecting the plurality of first filaments to form a plurality openings in the at least one side
wall,
wherein the at least one side wall has a generally cylindrical shape,
wherein the cage is made of a biodegradable material and the biodegradable material
includes a bone-growth enhancer.

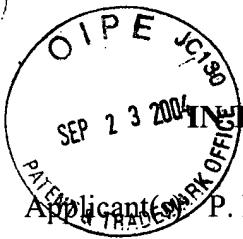
30. An implantable cage for holding an implantable material, the cage comprising:
a chamber configured and dimensioned to receive the implantable material; and
at least one side wall defining the chamber and including a plurality of first filaments
generally parallel to each other and a plurality of second filaments generally parallel to each other

and intersecting the plurality of first filaments to form a plurality openings in the at least one side wall,

wherein the cage is made of a biodegradable material and the biodegradable material includes a bone-growth enhancer.

31. The cage of claim 11 wherein the at least one side wall includes a plurality of first filaments generally parallel to each other and a plurality of second filaments generally parallel to each other and intersecting the plurality of first filaments to form a plurality of openings in the at least one side wall.

32. The cage of claim 31 wherein the cage is made of a material that includes a bone growth enhancer.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) P. Bonutti

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Group Art Unit: 3738

For: TISSUE STABILIZATION METHOD

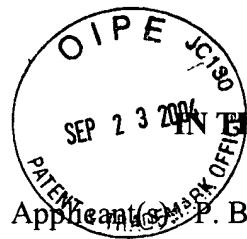
Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/793,266 (780-A04-006-17)**

1. A device for stabilizing tissue comprising a fastener having an elongated member at least partially made of an expandable material.
2. A device as defined in claim 1 wherein the expandable material expands by imbibing liquid.
3. A device as defined in claim 2 wherein the elongated member includes proximal and distal portions and at least the distal portion is made of the expandable material.
4. A device as defined in claim 3 wherein at least the distal portion is threaded.
5. A device as defined in claim 4 wherein the proximal portion includes an unthreaded projection.
6. A device as defined in claim 5 wherein the unthreaded projection has a hexagonal cross-sectioned.
7. A device as defined in claim 1 wherein the expandable material expands after being compressed.

8. A device as defined in claim 7 wherein the elongated member includes proximal and distal portions and at least the distal portion is made of the expandable material.
9. A device as defined in claim 8 wherein at least the distal portion is threaded.
10. A device as defined in claim 9 wherein the proximal portion includes an unthreaded projection.
11. A device as defined in claim 10 wherein the unthreaded projection has a hexagonal cross-sectioned.
12. A method of stabilizing tissue with the device of claim 1, the method comprising:
 - positioning a distal portion of the fastener in tissue;
 - positioning an implant adjacent the tissue such that a proximal portion of the fastener extends into the implant; and
 - expanding the expandable material of the fastener.
13. The method of claim 12 wherein expanding the expandable material of the fastener includes expanding the expandable material by imbibing liquid.
14. The method of claim 13 wherein expanding the expandable material by imbibing liquid includes expanding the expandable material radially outward.
15. The method of claim 14 wherein expanding the expandable material radially outward includes expanding the expandable material to lock the fastener into the tissue.
16. The method of claim 12 wherein positioning the distal portion of the fastener in tissue includes screwing a threaded section of the fastener into the tissue.

17. The method of claim 12 further including compressing the expandable material of the fastener and wherein expanding the expandable material of the fastener includes expanding the expandable material after compressing the expandable material.
18. The method of claim 17 wherein expanding the expandable material after compressing the expandable material includes expanding the expandable material radially outward.
19. The method of claim 18 wherein expanding the expandable material radially outward includes expanding the expandable material to lock the fastener into the tissue.
20. The method of claim 17 further including expanding the expandable material of the fastener by imbibing liquid.



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For: TISSUE STABILIZATION METHOD

Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/793,265 (780-A04-006-18)**

1. An implant used for stabilizing body tissue comprising:
a core at least partially formed of a material which expands by imbibing fluid, and
a retainer at least partially enclosing the core.
2. An implant as defined in claim 1 wherein the core is at least partially formed of a desiccated material.
3. An implant as defined in claim 2 wherein the retainer includes a plurality of crossed filaments.
4. An implant as defined in claim 3 wherein the retainer includes a plurality of openings.
5. An implant as defined in claim 4 wherein the retainer is at least partially made of a polymeric material.
6. An implant as defined in claim 1 wherein the core is at least partially formed of desiccated allograft material.
7. An implant as defined in claim 6 wherein the retainer is a cage.

8. An implant as defined in claim 7 wherein the retainer includes a plurality of openings.
9. An implant as defined in claim 8 wherein the retainer is at least partially made of ceramic.
10. An implant as defined in claim 9 wherein the retainer includes bone growth enhancers.
11. An implant as defined in claim 10 wherein the retainer includes hydroxyapatite.
12. An implant as defined in claim 1 wherein the core is at least partially formed of a biodegradable material.
13. An implant as defined in claim 12 wherein the biodegradable material is desiccated.
14. An implant as defined in claim 13 wherein the retainer is a mesh.
15. An implant as defined in claim 14 wherein the retainer includes a plurality of openings.
16. An implant as defined in claim 15 wherein the retainer is at least partially made of composite material.
17. An implant used for stabilizing body tissue comprising:
a core at least partially formed of a material which expands after being compressed, and
a retainer at least partially enclosing the core.
18. An implant as defined in claim 17 wherein the core is at least partially formed of a biodegradable material.
19. An implant as defined in claim 18 wherein the retainer includes a plurality of longitudinal filaments.

20. An implant as defined in claim 19 wherein the retainer includes a plurality of openings.

21. An implant as defined in claim 20 wherein the retainer is at least partially formed of metal.

22. An implant as defined in claim 17 wherein the core is at least partially formed of a material which expands by imbibing fluid.

23. An implant as defined in claim 22 wherein the material which expands by imbibing fluid is desiccated.



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For: TISSUE STABILIZATION METHOD

Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/793,287 (780-A04-006-19)**

1. A method of making a tissue graft material comprising:
placing body tissue and a blood component in a chamber; and
extruding the body tissue and blood component from an opening in the chamber to form
the tissue graft material.
2. The method of claim 1 further including implanting the tissue graft material into a
patient.
3. The method of claim 2 further including obtaining the blood component by separating the
blood component from blood.
4. The method of claim 3 wherein the blood component is separated by centrifugation of the
blood.
5. The method of claim 4 wherein the blood component is autogenic.
6. The method of claim 5 wherein the body tissue is bone.
7. The method of claim 6 wherein the bone is allogenic.

8. The method of claim 7 wherein extruding the body tissue and blood component includes extruding the body tissue and blood component through the opening in a desired shape.
9. The method of claim 8 wherein extruding the body tissue and blood component in a desired shape includes pushing the body tissue and blood component through the opening using a ram.
10. The method of claim 9 wherein pushing the body tissue and blood component with a ram includes increasing the density of the body tissue and blood component.
11. The method of claim 10 further including placing an additional material in the chamber, wherein the additional material is selected from the group consisting of an antibiotic, an apatite, a growth enhancer, fibrin, gelatin, a polysaccharide, synthetic bone material, a polymer, and a combination thereof.
12. A method of making a tissue graft material comprising:
placing synthetic tissue material and a blood component in a chamber; and
extruding the synthetic tissue material and blood component from an opening in the chamber to form the tissue graft material.
13. The method of claim 12 further including implanting the tissue graft material into a patient.
14. The method of claim 13 further including obtaining the blood component by separating the blood component from blood.
15. The method of claim 14 wherein the blood component is separated by centrifugation of the blood.
16. The method of claim 15 wherein the blood component is autogenic.

17. The method of claim 16 wherein the synthetic tissue material is synthetic bone.
18. The method of claim 17 wherein extruding the synthetic tissue material and blood component includes extruding the synthetic tissue material and blood component through the opening in a desired shape.
19. The method of claim 18 wherein extruding the synthetic tissue material and blood component in a desired shape includes pushing the synthetic tissue material and blood component through the opening using a ram.
20. The method of claim 19 further including placing an additional material in the chamber, wherein the additional material is selected from the group consisting of an antibiotic, an apatite, a growth enhancer, fibrin, gelatin, a polysaccharide, a polymer, and a combination thereof.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti Confirmation No.: 9219
Application No.: 09/988,954 Attorney Docket No: 780-A02-006-11
Filed: November 21, 2001 Group Art Unit: 3738
For: TISSUE STABILIZATION METHOD Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 09/872,526 (780-A02-014-7)**

36. A method of using body tissue, said method comprising the steps of removing fetal tissue from a donor through a percutaneous incision by cutting fetal tissue to separate portions of the fetal tissue from other portions of the donor and moving the separated portions of fetal tissue along a passage under the influence of suction, and implanting the separated portions of fetal tissue in a patient.

38. The method of claim 36 wherein rotating motion is used to cut the fetal tissue.

39. The method of claim 36 wherein reciprocating motion is used to cut the fetal tissue.

40. The method of claim 36 further comprising the step of irrigating the fetal tissue.

41. The method of claim 40 wherein the irrigation and suction alternate.

42. The method of claim 40 wherein the irrigation and suction occur substantially simultaneously.

43. The method of claim 36 wherein the passage includes a filter.

44. The method of claim 36 further including the step of centrifuging the separated portions of the fetal tissue.

45. A method of using body tissue, said method comprising the steps of removing fetal tissue from a donor through a percutaneous incision by cutting fetal tissue to separate portions of the fetal tissue from other portions of the donor and moving the separated portions of fetal tissue along a passage under the influence of suction, and implanting the separated portions of fetal tissue in a patient, wherein prior to implantation the separated portions of fetal tissue are combined with a material selected from the group consisting of tissue grafts, collagen, antibiotics, and bone growth promoting substances.

46. The method of claim 45 wherein the bone growth promoting substances are hydroxyapatite or tricalcium phosphate.

47. The method of claim 36 wherein an adhesive element is added to the separated portions of fetal tissue.

48. The method of claim 47 wherein the adhesive element is blood or fibrin.

49. A method of using body tissue, said method comprising the steps of removing fetal tissue from a donor through a percutaneous incision by cutting fetal tissue to separate portions of the fetal tissue from other portions of the donor and moving the separated portions of fetal tissue along a passage under the influence of suction, adding the separated portions of fetal tissue to a biodegradable material, and implanting the separated portions of fetal tissue in a patient.

50. The method of claim 36 further comprising the step of adding the separated portions of fetal tissue to a polymer.

51. The method of claim 36 further comprising the step of sealing the separated portions of fetal tissue in the patient.

52. The method of claim 36 wherein at least one of the steps of cutting and implanting is performed under x-ray guidance.

53. The method of claim 36 wherein at least one of the steps of cutting and implanting is performed through a cannula.

54. The method of claim 36 wherein at least one of the steps of cutting and implanting is performed under endoscopic, arthroscopic, or fiber optic guidance.

55. The method of claim 36 wherein the separated portions of fetal tissue are formed into an implant prior to implantation.

56. The method of claim 36 wherein the donor is the patient.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

Confirmation No.: 9219

Application No.: 09/988,954

Attorney Docket No: 780-A02-006-11

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Group Art Unit: 3738

For: TISSUE STABILIZATION METHOD

Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/003,996 (780-A02-014-8)**

36. A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of removing tissue from a first location in the patient's body, separating one or more components from at least a portion of the removed tissue, thereafter packing the removed tissue into a desired shape, and thereafter implanting the packed tissue at a second location in the patient's body, wherein the removed tissue includes blood and other body tissue.

37. A surgical procedure as set forth in claim 36 wherein said step of separating one or more components from the removed tissue includes centrifuging at least a portion of the removed tissue.

38. A surgical procedure as set forth in claim 36 further including the step of adding a substance to the removed tissue after separating one or more components from the removed tissue and prior to implanting the packed tissue at a second location in the patient's body.

39. A surgical procedure as set forth in claim 36 wherein said step of removing tissue from a first location in a patient's body includes cutting body tissue at the first location and moving the body tissue away from the first location under the influence of suction.

40. A surgical procedure to be conducted on a patient, said surgical procedure comprising the

steps of removing tissue from a first location in the patient's body, separating one or more components from at least a portion of the tissue removed from the patient's body, and implanting the tissue at a second location in the patient's body after separating one or more components from at least a portion of the tissue, wherein said step of removing tissue from a first location in a patient's body includes cutting body tissue at the first location and moving the body tissue away from the first location under the influence of suction and wherein said step of cutting body tissue includes rotating a cutting tool under the influence of force transmitted through an elongated member which is at least partially enclosed by a tubular member, said step of moving the body tissue away from the first location under the influence of suction includes moving body tissue cut by the rotating cutting tool along the tubular member under the influence of suction, wherein the elongated member is flexible such that the cutting tool can be guided.

41. A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of removing tissue from a first location in the patient's body, separating one or more components from at least a portion of the tissue removed from the patient's body, and implanting the tissue at a second location in the patient's body after separating one or more components from at least a portion of the tissue, wherein said step of implanting the tissue at the second location includes inserting a cannula into the patient's body, moving a surgical instrument through the cannula, removing tissue from the second location, said step of removing tissue from the second location includes using the surgical instrument inserted through the cannula, and, thereafter, performing said step of inserting tissue removed from the first location in the patient's body at the second location in the patient's body.

42. A surgical procedure as set forth in claim 36 wherein said step of separating one or more components from the removed tissue includes separating one or more components from blood removed from the patient's body, said step of implanting the packed tissue at a second location in the patient's body includes implanting one or more components of the blood removed from the patient's body.

43. A surgical procedure as set forth in claim 36 wherein said step of separating one or more components from the removed tissue includes separating at least a first component from blood

removed from the patient's body, said step of implanting the packed tissue at a second location in the patient's body includes implanting the blood removed from the patient's body after removing at least the first component from the blood and implanting at least a portion of the other body tissue removed from the patient's body.

44. A surgical procedure as set forth in claim 36 wherein said step of separating one or more components from the removed tissue includes removing at least a first component from the blood removed from the patient's body, and said step of implanting the packed tissue at the second location includes implanting at least the blood from which at least the first component has been removed.

46. A surgical procedure as set forth in claim 36 wherein said step of separating one or more components from the removed tissue includes filtering the blood and other body tissue removed from the first location, said step of implanting the packed tissue at a second location is performed after filtering the blood and other body tissue removed from the first location.

47. A surgical procedure as set forth in claim 36 wherein said step of separating one or more components from the removed tissue includes moving the blood and other body tissue removed from the first location into a trap, said step of implanting the packed tissue at a second location is performed after moving the blood and other body tissue removed from the first location into the trap.

49. A surgical procedure as set forth in claim 36 wherein said step of removing tissue from a first location in a patient's body includes inserting a first tubular member into a patient's body and moving the removed tissue from the first location in the patient's body through the first tubular member to a location outside of the patient's body, said step of implanting the packed tissue at a second location in the patient's body includes inserting a second tubular member into the patient's body and moving the packed tissue through the second tubular member.

51. A surgical procedure as set forth in claim 53 further including the step of separating one or more components from at least a portion of the body tissue moved through the first tubular

member prior to performance of said step of moving body tissue through the second tubular member to the second location in the patient's body.

52. A surgical procedure as set forth in claim 53 further including the step of centrifuging at least a portion of the body tissue moved through the first tubular member to separate one or more components from the body tissue prior to performing said step of moving the body tissue through the second tubular member.

53. A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of inserting a first tubular member into the patient's body, moving body tissue from a first location in the patient's body through the first tubular member to a location outside of the patient's body, inserting a second tubular member into the patient's body, and moving at least a portion of the body tissue through the second tubular member to a second location in the patient's body, wherein a substance is added to the body tissue after moving the body tissue from the first location through the first tubular member to a location outside of the patient's body and prior to moving the body tissue through the second tubular member, and wherein the added substance is a bone growth promoter.

54. A surgical procedure as set forth in claim 53 wherein said step of moving the body tissue from the first location through the first tubular member includes moving the body tissue through the first tubular member under the influence of suction.

55. A surgical procedure as set forth in claim 53 further including the step of cutting body tissue at the first location with a cutting tool which is driven under the influence of force transmitted through the first tubular member.

56. A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of inserting a first tubular member into the patient's body, moving body tissue from a first location in the patient's body through the first tubular member to a location outside of the patient's body, inserting a second tubular member into the patient's body, moving a surgical instrument through the second tubular member, removing tissue from a second location with the

surgical instrument, and moving at least a portion of the body tissue through the second tubular member to the second location in the patient's body.

57. A surgical procedure as set forth in claim 53 wherein said step of moving body tissue from a first location in the patient's body through the first tubular member includes moving blood from the first location in the patient's body through the first tubular member, said surgical procedure further includes separating one or more components from the blood, said step of moving body tissue through the second tubular member to the second location in the patient's body includes moving the blood from which one or more components have been removed through the second tubular member to the second location in the patient's body.

58. A surgical procedure as set forth in claim 53 wherein said step of moving tissue from the first location in the patient's body through a first tubular member includes moving blood and pieces of other tissue through the first tubular member, said surgical procedure further includes filtering the blood and other tissue moved through the first tubular member, said step of moving body tissue through the second tubular member is performed after filtering the blood and other tissue.

59. A surgical procedure as set forth in claim 53 wherein said step of moving tissue from the first location in the patient's body through a first tubular member includes moving blood and pieces of other tissue through the first tubular member, said surgical procedure further includes moving the blood and other tissue into a trap, said step of moving body tissue through the second tubular member is performed after moving the blood and other tissue into a trap.

60. A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of inserting a first tubular member into the patient's body, moving body tissue from a first location in the patient's body through the first tubular member to a location outside of the patient's body, packing tissue moved through the first tubular member to form a body of packed tissue, inserting a second tubular member into the patient's body, and moving the body of packed tissue through the second tubular member to a second location in the patient's body.

69. A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of cutting body tissue at a first location in a patient's body, moving blood and other body tissue along a first tubular member in a direction away from the first location in the patient's body to a location outside of the patient's body, separating one or more components from at least one of the blood and other body tissue at a location outside of the patient's body, thereafter, packing the blood and other body tissue to form a packed tissue mass, moving the packed tissue mass along a second tubular member in a direction toward a second location in the patient's body, and implanting the packed tissue mass at the second location in the patient's body.

70. A surgical procedure as set forth in claim 69 wherein said step of separating one or more components from at least one of the blood and other body tissue includes centrifuging the blood.

71. A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of cutting body tissue at a first location in a patient's body, moving blood and other body tissue along a first tubular member in a direction away from the first location in the patient's body to a location outside of the patient's body, separating one or more components from at least one of the blood and other body tissue at a location outside of the patient's body, thereafter, moving the blood and other body tissue along a second tubular member in a direction toward a second location in the patient's body, and implanting the blood and other body tissue at the second location in the patient's body wherein said step of separating one or more components from at least one of the blood and other body tissue includes centrifuging the other body tissue.

72. A surgical procedure as set forth in claim 71 wherein said step of separating one or more components from at least one of the blood and other body tissue includes centrifuging the blood.

73. A surgical procedure as set forth in claim 69 further including the step of adding a substance to the packed tissue mass prior to moving the packed tissue mass along the second tubular member.

74. A surgical procedure as set forth in claim 69 wherein said step of moving the packed tissue mass along a first tubular member includes moving the packed tissue mass under the

influence of suction.

75. A surgical procedure as set forth in claim 69 wherein said step of cutting body tissue at the first location in a patient's body includes rotating a cutting tool under the influence of force transmitting through the first tubular member.

76. A surgical procedure as set forth in claim 69 further including the steps of moving a surgical instrument through the second tubular member and removing the tissue from the second location before moving the packed tissue mass along the second tubular member.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

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For: TISSUE STABILIZATION METHOD

Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/004,905 (780-A02-014-10)**

37. A method as set forth in claim 42 wherein said step of rotating the inner member relative to the outer member includes rotating the inner member in first and second directions relative to the outer member while the shaft is maintained in the desired configuration under the influence of the rigidity of the outer member.

38. A method as set forth in claim 42 wherein said step of moving body tissue cut from the patient along a passage within the shaft includes conducting the body tissue along a path disposed between the inner and outer members.

39. A method as set forth in claim 42 wherein said step of moving body tissue cut from the patient along a passage within the shaft includes conducting the body tissue along a path disposed within the inner member.

40. A method as set forth in claim 42 further including the steps of positioning a guide rod relative to tissue in the patient's body and moving the cutting element along the guide rod into engagement with the patient's body tissue.

41. A method as set forth in claim 42 wherein said step of moving body tissue cut from the patient along a passage within the shaft includes moving the tissue cut from the patient in a first direction along the passage within the shaft, said method further includes moving fluid along the passage within the shaft in a second direction opposite to the first direction.

42. A method of operating on a patient, said method comprising the steps of providing a tool having a shaft with a flexible inner member which is rotatable about a central axis of the shaft and an outer member which extends along and encloses the inner member along substantially the entire length of the inner member, the outer member has greater rigidity than the inner member, bending the inner and outer members to a desired configuration, rotating the inner member relative to the outer member, maintaining the shaft in the desired configuration under the influence of the rigidity of the outer member during rotation of the inner member, cutting the patient's body tissue with a cutting element connected with the inner member during rotation of the inner member, moving body tissue cut from the patient along a passage within the shaft while the shaft is maintained in the desired configuration under the influence of the rigidity of the outer member, and removing body tissue from a flow of fluid conducted along the passage within the shaft.

43. A method as set forth in claim 42 further including the steps of positioning a guide rod relative to tissue in the patient's body, positioning the guide rod in the shaft of the tool, and sliding the shaft of the tool along the guide rod until the cutting element connected with a leading end portion of the inner member is disposed in a desired position relative to the patient's body tissue.

44. A method of operating on a patient, said method comprising the steps of providing a tool having a shaft with a flexible inner member which is rotatable about a central axis of the shaft and an outer member which extends along and encloses the inner member along substantially the entire length of the inner member, the outer member has greater rigidity than the inner member, bending the inner and outer members to a desired configuration, rotating the inner member relative to the outer member, maintaining the shaft in the desired configuration under the

influence of the rigidity of the outer member during rotation of the inner member, cutting the patient's body tissue with a cutting element connected with the inner member during rotation of the inner member, moving body tissue cut from the patient along a passage within the shaft while the shaft is maintained in the desired configuration under the influence of the rigidity of the outer member, positioning a guide rod relative to tissue in the patient's body, positioning the guide rod in the shaft of the tool, sliding the shaft of the tool along the guide rod until the cutting element connected with a leading end portion of the inner member is disposed in a desired position relative to the patient's body tissue, and bending the guide rod to a desired configuration, said step of sliding the shaft of the tool along the guide rod is performed while maintaining the guide rod bent to the desired configuration.

50. A method as set forth in claim 42 wherein the cutting is performed under x-ray guidance.

51. A method as set forth in claim 42 wherein the cutting is performed under endoscopic, arthroscopic, or fiber optic guidance.

54. A method as set forth in claim 41 wherein the cut tissue and fluid movement alternate.

55. A method as set forth in claim 42 wherein the passage includes a filter.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

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Group Art Unit: 3738

For: TISSUE STABILIZATION METHOD

Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/104,250 (780-A02-014-12)**

36. A method of using human tissue, said method comprising the steps of removing tissue from a human patient, said step of removing tissue from the human patient includes removing blood from the human patient, centrifuging blood removed from the human patient to at least partially remove one or more components from the blood, and implanting in the patient a blood component remaining after centrifuging the blood.

37. A method as set forth in claim 36 wherein said step of implanting a blood component in the patient includes implanting collagen along with the blood component.

38. A method as set forth in claim 36 wherein said step of implanting a blood component in the patient includes implanting tissue graft material along with the blood component.

39. A method as set forth in claim 36 wherein said step of implanting a blood component in the patient includes implanting antibiotics along with the blood component.

40. A method as set forth in claim 36 wherein said step of implanting a blood component in the patient includes implanting hydroxyapatite along with the blood component.

41. A method as set forth in claim 36 wherein said step of implanting a blood component in the patient includes implanting the blood component in a bone in the patient's body.
42. A method as set forth in claim 36 wherein said step of implanting a blood component in the patient includes positioning the blood component in a biodegradable retainer and positioning the biodegradable retainer in the patient's body.
43. A method as set forth in claim 36 wherein said step of implanting a blood component in the patient includes moving a biodegradable bag into the patient.
44. A method as set forth in claim 36 wherein said step of implanting a blood component in the patient includes moving the blood component through a cannula to a desired location in the human patient.
45. A method as set forth in claim 36 wherein said step of removing tissue from a human patient includes conducting the tissue from the patient under the influence of suction.
46. A method as set forth in claim 36 wherein said step of removing tissue from a human patient includes rotating a cutting tool to cut tissue at a first location in the human patient and moving the cut tissue from the first location in the human patient.
48. A method of using human tissue, said method comprising the steps of removing tissue from a human patient, said step of removing tissue from the human patient includes removing collagen from the human patient, separating at least a portion of the collagen removed from the human patient from one or more tissue components, and implanting the collagen in the human patient, wherein said step of removing tissue from the human patient includes removing blood from the human patient, separating at least a portion of at least one component from the blood removed from the human patient, said step of

implanting the collagen in the human patient includes implanting blood from the human patient after separating at least a portion of at least one component from the blood.

49. A method as set forth in claim 48 wherein said step of implanting collagen in the human patient includes implanting tissue graft material along with the collagen.

50. A method as set forth in claim 48 wherein said step of implanting collagen in the human patient includes implanting antibiotics along with the collagen.

51. A method as set forth in claim 48 wherein said step of implanting collagen in the patient includes implanting a tissue growth inductive factor along with the collagen.

52. A method of using human tissue, said method comprising the steps of removing tissue from a human patient, said step of removing tissue from the human patient includes removing collagen from the human patient, separating at least a portion of the collagen removed from the human patient from one or more tissue components, and implanting the collagen in the human patient, wherein said step of implanting collagen in the patient includes positioning the collagen in a biodegradable retainer and positioning the biodegradable retainer in the patient's body.

53. A method of using human tissue, said method comprising the steps of removing tissue from a human patient, said step of removing tissue from the human patient includes removing collagen from the human patient, separating at least a portion of the collagen removed from the human patient from one or more tissue components, and implanting the collagen in the human patient, wherein said step of implanting collagen in the patient includes moving a biodegradable bag into the patient.

54. A method as set forth in claim 48 wherein said step of implanting collagen in the human patient includes moving the collagen through a cannula to a desired location in the human patient.

55. A method as set forth in claim 48 wherein said step of removing tissue from a human patient includes conducting the tissue under the influence of suction.

56. A method of using human tissue, said method comprising the steps of removing tissue from a first location in a human patient, and implanting at least a portion of the tissue at a second location in the human patient, said step of implanting at least a portion of the tissue at a second location in the human patient includes moving a biodegradable bag to the second location in the human patient.

57. A method as set forth in claim 56 wherein said step of implanting the tissue at the second location in the human patient includes moving at least a portion of the tissue removed from the first location in the human patient to the second location in the human patient.

58. A method as set forth in claim 56 wherein said step of removing tissue from a first location in a human patient includes removing blood from the human patient, said method further includes centrifuging blood removed from the human patient to at least partially remove one or more components from the blood, said step of implanting the tissue at the second location in the human patient includes moving at least a portion of the blood to the second location in the human patient after centrifuging the blood.

59. A method as set forth in claim 56 wherein said step of moving the biodegradable bag to the second location in the human patient includes moving the biodegradable bag through a cannula.

60. A method as set forth in claim 56 wherein said step of implanting at least a portion of the tissue at the second location in the human patient includes moving the human tissue through a cannula with the human tissue in the biodegradable bag.

61. A method of utilizing human tissue, said method comprising the steps of: percutaneously harvesting tissue from bone of a human donor;

conveying the harvested tissue to a location outside the body of the donor through a sterile passage;

collecting the harvested tissue in a container operatively associated with the sterile passage;

centrifuging blood obtained from the donor to separate a blood component;

combining the blood component with the harvested tissue;

placing the combined blood component and harvested tissue in a form to form a tissue graft plug; and

implanting the tissue graft plug into a human recipient.

62. A method as set forth in claim 61 wherein the tissue graft plug is implanted into a bone of the recipient.

63. A method as set forth in claim 62 wherein the donor and recipient are the same individual.

64. A method as set forth in claim 63 further comprising the step of separating out at least one component from the harvested tissue prior to combining the blood component and harvested tissue.

65. A method as set forth in claim 64 wherein a filter is used for the separation step.

66. A method as set forth in claim 64 wherein centrifugation is used for the separation step.

67. A method as set forth in claim 63 wherein the tissue graft plug includes viable tissue.

68. A method as set forth in claim 63 wherein the blood component is fibrin.

69. A method as set forth in claim 63 further comprising the step of adding a bone growth promoting substance to the combined blood component and harvested tissue.
70. A method as set forth in claim 69 wherein the bone growth promoting substance is hydroxyapatite or tricalcium phosphate.
71. A method as set forth in claim 63 further comprising the step of adding collagen to the combined blood component and harvested tissue.
72. A method as set forth in claim 63 further comprising the step of adding an antibiotic to the combined blood component and harvested tissue.
73. A method as set forth in claim 63 wherein the blood is obtained from the harvested tissue.
74. A method as set forth in claim 62 further comprising the step of passing the harvested tissue through a filter.
75. A method as set forth in claim 74 wherein the tissue graft plug includes viable tissue.
76. A method as set forth in claim 75 wherein the donor and recipient are the same individual.



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Applicant(s): P. Bonutti

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For: TISSUE STABILIZATION METHOD

Examiner: P. Prebilic

**CLAIMS
OF
CO-PENDING APPLICATION 10/233,866 (780-A02-014-13)**

1. A surgical method comprising the steps of:
creating a space in a tissue; and
introducing a biodegradable sac containing tissue into the created space.
2. The method of claim 1 wherein the sac contains liquid.
3. A surgical method comprising the steps of:
creating a space in a tissue; and
introducing a biodegradable sac containing liquid into the created space,
wherein the sac is closed by clamping, crimping, or heat sealing.
4. The method of claim 2 wherein the sac contains a material selected from the group consisting of tissue grafts, collagen, antibiotics, and bone growth promoting substances.
5. A surgical method comprising the steps of:
creating a space in a tissue; and
introducing a biodegradable sac into the created space,
wherein the space is created by inserting an inflatable member into the tissue and inflating

the inflatable member.

6. The method of claim 5 further comprising the step of at least partially deflating the inflatable member.
7. The method of claim 6 further comprising the step of removing the inflatable member from the tissue prior to introduction of the sac.
8. The method of claim 5 further comprising the step of inserting at least a portion of a sleeve into a patient's body and wherein the inflatable member is inserted into tissue through the sleeve.
9. The method of claim 8 further comprising the step of guiding the sleeve to the tissue with a guide wire.
10. The method of claim 8 further comprising the step of removing tissue fragments from the tissue.
11. The method of claim 8 wherein the sleeve is inserted percutaneously through skin.
12. The method of claim 5 wherein the tissue is bone tissue.
13. The method of claim 5 wherein the tissue is selected from the group consisting of bone, cartilage, muscle, and fetal tissue.
14. The method of claim 5 wherein at least one of the steps of inserting and inflating is performed under x-ray guidance.
15. The method of claim 5 wherein at least one of the steps of inserting and inflating is performed under endoscopic, arthroscopic, or fiber optic guidance.

16. The method of claim 5 wherein the inflatable member includes a plurality of inflatable elements.
17. The method of claim 16 wherein the inflatable elements are selectively inflated so that the inflatable member assumes a predetermined shape.
18. The method of claim 17 wherein a microprocessor is used to control the selective inflation.
19. The method of claim 5 wherein the inflatable member is flexible and substantially straight when deflated and assumes a preformed shape when inflated.
20. The method of claim 19 wherein the inflatable member bends radially outward.
21. A surgical method comprising the steps of:
inserting at least a portion of an elongate member into tissue;
inflating an inflatable member extending beyond a distal end of the elongate member so that the inflatable member engages a surface of tissue when inflated;
at least partially deflating the inflatable member; and
introducing a sac into at least a portion of space previously occupied by the inflatable member.
22. The method of claim 21 further comprising the step of inserting at least a portion of a sleeve into a patient's body and wherein the elongate member is inserted into tissue through the sleeve.
23. The method of claim 22 wherein the elongate member includes a plurality of inflatable elements.
24. The method of claim 23 wherein the inflatable elements are substantially accordion shaped and expand in length when inflated.

25. The method of claim 23 wherein the inflatable elements are selectively inflated so that the elongate member assumes a predetermined shape.
26. The method of claim 25 wherein a microprocessor is used to control the selective inflation.
27. The method of claim 21 wherein the inflatable member is flexible and substantially straight when deflated and assumes a preformed shape to engage a surface of tissue when inflated.
28. The method of claim 27 wherein the inflatable member bends radially outward.
29. The method of claim 21 further comprising the step of guiding the elongate member to tissue with a guide wire.
30. The method of claim 21 further comprising the step of removing tissue fragments from tissue.
31. The method of claim 21 wherein the elongate member is inserted percutaneously through skin.
32. The method of claim 21 wherein the surface of tissue includes tissue selected from the group consisting of bone, cartilage, muscle, and fetal tissue.
33. The method of claim 21 wherein at least one of the steps of inserting and inflating is performed under x-ray guidance.
34. The method of claim 21 wherein at least one of the steps of inserting and inflating is performed under endoscopic, arthroscopic, or fiber optic guidance.

35. A surgical method comprising the steps of:
implanting a pouch made of a biodegradable material into a body of a patient;
introducing a liquid into the pouch; and
closing the pouch to retain the liquid in the pouch.
36. The method of claim 35 wherein the pouch is closed by clamping, crimping, or heat sealing.
37. The method of claim 35 wherein the pouch contains a calcium-containing material.
38. The method of claim 35 wherein the pouch is implanted into bone.
39. The method of claim 35 wherein the pouch is implanted into a space surgically created in a tissue.
40. The method of claim 39 wherein the space is created by inserting an inflatable member into the tissue and inflating the inflatable member.
41. The method of claim 1 wherein the sac contains a material selected from the group consisting of tissue grafts, collagen, antibiotics, and bone growth promoting substances.
42. The method of claim 1 wherein creating a space in the tissue includes creating a space in bone.
43. The method of claim 1 wherein the tissue in the sac is selected from the group consisting of bone, cartilage, muscle, and fetal tissue.
44. The method of claim 1 wherein at least one of the steps of creating and introducing is performed under x-ray guidance.
45. The method of claim 1 wherein at least one of the steps of creating and introducing is

performed under endoscopic, arthroscopic, or fiber optic guidance.

46. The method of claim 1 wherein the sac contains a calcium-containing material.
47. The method of claim 3 wherein the tissue is selected from the group consisting of bone, cartilage, muscle, and fetal tissue.
48. The method of claim 3 wherein at least one of the steps of creating and introducing is performed under x-ray guidance.
49. The method of claim 3 wherein at least one of the steps of creating and introducing is performed under endoscopic, arthroscopic, or fiber optic guidance.
50. The method of claim 3 wherein the sac contains a calcium-containing material.